Page 1, lines 6 through 9 delete the priority statement and insert:

"This is a continuation-in-part of co-pending Application No. 09/097078 filed June 12, 1998, issued May 30, 2000 as US Patent 6,070,126, which claims benefit of US Provisional Application Serial No. 60/049,613 filed June 13, 1997. This application also claims the benefit of US Provisional Application Serial No. 60/130,230 filed on April 20, 1999."

Remarks

Priority

Applicant has amended the statement of priority to reflect the issuance of a patent from a parent application.

§ 112 Rejections

Examiner has rejected claims 12 and 19 under § 112 (second paragraph) as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claims 12 and 19 are rejected because they depend from a non-elected claim. Claims 12 and 19 have been amended to incorporate all the limitations of the claims from which they depend. Thus, amended claims 12 and 19 now particularly point out and distinctly claim the subject matter of applicant's invention. The rejection under § 112 (second paragraph) should therefore be withdrawn.

§ 102(b) Rejections

The examiner has rejected claims 12 and 19 under 35 USC 102 (b) as being anticipated by Kokolus et al (WO 96/40754) hereinafter referred to as Kokolus –WO. According to 35 U.S.C. § 102(b)

> A person shall be entitled to a patent unless
> (b) th inv ntion was patented or described in a printed publication in this of a foreign country or in public use or

on sal in this country, more than one year prior to the date of application for patent in the United States. (Emphasis added.)

Applicant respectfully notes the publication date of the Kokolus-WO application is December 19, 1996. Accordingly, an application filed before December 19, 1997 will overcome the one year bar of § 102(b). As noted in the originally filed application and in the amended priority statement *supra*, the filing date of U.S. Provisional Application Serial No. 60/049,613, June 13, 1997, is well within the one year grace period allowed by § 102(b). According to MPEP 706.02, in the case of a C-I-P application entitled to priority under 35 U.S.C. § 119(e), any claims which are fully supported under 35 U.S.C. § 112 by the earlier parent application have the effective filing date of that earlier parent. Applicant asserts that the claims of the instant applicant are fully supported under § 112 by U.S. Provisional Application Serial No. 60/049,613 from which the instant application Therefore, the rejection of amended claims 12 and 19 as anticipated by Kokolus-WO should be withdrawn.

The Examiner has rejected claims 12 and 19 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,807,978 to Kokolus, et. al., hereinafter Kokolus '978. As suggested in Examiner's remarks, applicant has attached as Exhibit A an affidavit under 37 C.F.R. § 1.132 declaring that applicant is the sole inventor of the invention disclosed but not claimed in Kokolus '978. Therefore, Examiner's rejection of the instant invention under §102(e) should be withdrawn as Kokolus '978 fails as a reference under § 102(e) as the invention disclosed in Kokolus '978 was not invented by "another" as required in § 102(e).

The examiner has rejected claims 12 and 19 under 35 U.S.C. 102 (b) as being anticipated by Dowell et al, U.S. Patent 5,599,677 hereinafter referred to as Dowell '677. This rejection is respectfully traversed because Dowell '677 does not explicitly teach each and every limitation in applicant's amended claims.

According to MPEP 2131 and 706.2
" A claim is anticipated only if each and very element as set forth in the claim is also found, either expressly or inherently described in a single prior art reference."

Applicant will point out, in the remarks below, how the properties of the assays claimed in amended claims 12 and 19 of the present invention, are distinct and mutually exclusive from the assay disclosed by Dowell '677.

The examiner rejects claims 12 and 19 on the grounds that allegedly Dowell '677 discloses an assay that is the same as the assay in claims 12 and 19. The assay disclosed in Dowell '677 measures the presence of free analyte and analyte bound in a complex with a binding molecule. Two different sets of antibodies are required in the Dowell '677 assay, one antisera that recognizes the free analyte and a second antisera that recognizes the complexed analyte. Both sets of antisera are specific for whole PSA protein. In contrast, the assay as defined in applicant's amended claims 12 and 19 is limited by the use of one type of antisera that is specific for a Ho-Hi-Ho epitope present in an analyte of a define length and characteristics.

Applicant has attached as Exhibit B an affidavit submitted under 37 C.F.R. § 1.132 disclosing data that demonstrates the use of only <u>one</u> antibody produced from a peptide with applicant's disclosed Ho-Hi-Ho amino acid sequences to measure both free or total PSA. This establishes that the antisera is not anticipated by Dowell '677 as only one antisera is necessary in the instant invention to measure free and total PSA while Dowell '677 requires two different sets of antisera, each set sensitive to a different antigen. Therefore, Examiner's rejection under § 102(b) as anticipated by Dowell '677 should be withdrawn and amended claims 12 and 19 passed to allowance.

V rsion with markings to how changes made

Please amend the following claims:

12. (Amended) A diagnostic testing method comprising the steps of:

(iii) providing a sample;

(iv) contacting said sample with antisera specific for a Ho-Hi-Ho epitope of contiguous amino acid residues from a polypeptide wherein said epitope is characterized by a hydrophobic-hydrophilic –hydrophobic motif having an optimal length of amino acid residues determined by a method [of claim 3] comprising the steps of:

a) assigning an average hydropathy value to each amino acid of a polypeptide;

b) generating a hydrophilicity plot using the average hydropathy value of each amino acid;

c) fitting a curve segment of the hydrophilicity plot to a negative cosine function, wherein a specific period number value of the negative cosine function equates to the number of amino acids in the curve segment, the period number increasing within a predetermined chosen period number range after each sequential lagging through the hydrophilicity plot thereby providing fit-correlation values for each curve segment across the linear sequence when using the specific period number value;

d) generating a potential Ho-Hi-Ho epitope set for each specific period number value within the chosen period number range, wherein each potential Ho-Hi-Ho epitope set contains potential Ho-Hi-Ho epitopes that have a fit-correlation value;

e) ranking each potential Ho-Hi-Ho epitope in the potential Ho-Hi-Ho epitope set according to positive fit-correlation values wherein the epitope having high st positive-fit correlation value is ranked number one thereby providing ranked Ho-Hi-Ho potential epitopes for each specific period number value;

f) examining the positioning of at least the highest ranked Ho-Hi-Ho potential epitopes of each set relative to the linear sequence of the plot of step (a) to determine at least one set of Ho-Hi-Ho potential epitopes that exhibit alternating positioning about an equilibrium position wherein the ranking values of the Ho-Hi-Ho potential epitopes coverage towards or diverge away from the equilibrium position; and

g) designating the Ho-Hi-Ho potential epitopes of the set having the most alternating ranking values that converge or diverge as the immunologically active epitopes which have an optimal length equating to numeric value of amino acid residues in the potential epitopes; and

(iii) detecting the binding of said antisera to a polypeptide in said sample.

19. (Amended) A diagnostic testing method comprising the steps of:

(i) providing a sample;

(ii) contacting said sample with antisera specific for a Ho-Hi-Ho epitope of contiguous amino acid residues from a polypeptide wherein said epitope is characterized by a hydrophobic-hydrophilic-hydrophobic motif having optimal length of amino acid residues determined [by] a method [of claim 15] comprising the steps of:

(a) fitting a hydrophilicity and/or hydrophobicity plot generated for the amino acid linear

sequence of a polypeptide to a mathematically generated continuous curve thereby generating potential epitope sets which include ranked potential epitopes having a specific number of amino acid residues, the mathematically generated curve having at least a maximum positive value;

(b) positioning the ranked potential epitopes for each set on the hydrophilicity and/or hydrophobicity plot to determine the oscillating behavior of the numeric values of ranked potential epitopes; and

(c) deeming the potential epitopes that exhibit the most alternating position about an equilibrium position when juxtaposed on the hydrophilicity and/or hydrophobicity plot as the theoretical epitopes and their optimal length corresponds to the specific number of amino acid residues in the set of ranked potential epitomes; and

(iii) detecting the binding of said antisera to a polypeptide in said sample.

In view of the foregoing discussion, it is respectfully submitt d that this case is in condition for allowance and such allowance is earnestly solicited.

Date: March 13, 2002

Respectfully submitted,

C. Richard Lohrman
Reg. No. 46,878
THE BILICKI LAW FIRM, P.C.
Furniture Mart Building, Suite 1000
111 West Second Street
Jamestown, NY 14701
Tel: (716)-664-5600

ATTORNEY FOR APPLICANT